IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

In re: C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation	**MDL No. 2187 2:10-md-2187**
In re: American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation	**MDL No. 2325 2:12-md-2325**
In re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation	**MDL No. 2326 2:12-md-2326**
In re: Ethicon Inc., Pelvic Repair System Products Liability Litigation	**MDL No. 2327 2:12-md-2327**

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' RESPONSE TO DEFENDANTS' POSITION STATEMENTS ON THE ACCESS TO AND EXCHANGE OF DOCUMENTS DISCOVERED IN OTHER PELVIC MESH MDLS PENDING BEFORE THIS COURT

COME NOW Plaintiffs in the pending MDLs, and file this response to Defendants' respective Position Statements on the Access to and Exchange of Documents Discovered in Other Pelvic Mesh MDLs Pending Before this Court, stating as follows:

A. The documents plaintiffs seek to use are plainly relevant to the claims asserted against the MDL defendants.

As detailed in Plaintiffs' Position Statement, there are many instances where a document produced in one MDL is relevant to a claim asserted in another MDL, particularly where consultant-physicians were engaged by more than one defendant to assist them in selling their products.[1] The defendants suggest that the use of another manufacturer's document would

[1] As recognized by the August 2011 Public Citizen Petition submitted to the FDA, despite a complete lack of long-term clinical data demonstrating that these invasive mesh devices were reasonably safe and

provide no basis for any questioning, and have no applicability to the underlying disputes, simply because the witness may not be familiar with the document.[2] Such an argument conveniently ignores the fundamental tenet of any company's success in sales: defending your brand. There are two well-recognized marketing concepts aimed at limiting a customer's trial of a competing brand (*e.g.*, preventing a doctor switching from one PFR device to another): attacking the competing product's benefits and highlighting the risks that customers run in switching to it.[3] There is ample evidence of both throughout thousands of defendants' e-mails and other documents.

In questioning the benefits of a new competitor's device, which none of the defendants dispute actually occurred, a 'defending' company seeks to reduce the appeal of the new product to physicians by eroding its support. If an established company could equip its employees through market research or advice from consultant-physicians to challenge the claims/purported benefits of a new entrant, then the new product's overall proposition erodes, and the likely trial by that doctor of the competing product declines.

Further, successful multi-billion companies, like the defendants, would internally highlight the risks associated with a new pelvic mesh product entering the market, when such risks could be readily identified.[4] This point is significant—when a defendant introduced a new pelvic mesh product on the market, the use of any documents in the deposition of the defendant's

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effective for transvaginal repair of pelvic organ prolapse, these devices were "heavily promoted by industry and their highly paid physician consultants."

[2] Of course, there are numerous examples of these consultant-physicians having actually authored the document itself telling each manufacturer what they wanted to hear, changing their tune when convenient. For example, a key opinion leader, previously retained by several of the defendants, conveyed his thoughts to the Group Product Manager at Boston Scientific about the "bad ideas" being developed by Ethicon in 2006, "and they know I feel that way." (BSCM05600045533-34 attached hereto as **"Exhibit 1"**).

[3] *See* Tim Calkins, *Defending Your Brand: How Smart Companies Use Defensive Strategy to Deal with Competitive Attacks*, Ch. 11 (Palgrave Macmillan 2012).

[4] *See id*.

employee related to the perceived flaws or risks internally addressed and known by *its competitor*, even if the individual questioned about a document was not the author, could undeniably lead to the discovery of admissible evidence.[5] Indeed, internal efforts by a defendant to leverage its products through its sales force (*i.e.*, Johnson & Johnson with the Prolift in 2005) by highlighting various weaknesses and to rebut the claims or improvements allegedly made by another defendant with a newer product (*i.e.*, Boston Scientific with the Pinnacle in 2008) could be used, at the very least, to confirm the accuracy of such contentions through the latter defendant's fact and/or expert witnesses. For example, in May of 2009, Ethicon was working on a "competitive sales aid" to inform its sales force about various "thoughts" in response to the "claims" being made by Boston Scientific with its Pinnacle product when it entered the market, including key concerns recognized by Ethicon's surgeons with the use of the Pinnacle. (ETH-48769 attached hereto as **"Exhibit 2"**). Plaintiffs should be entitled to determine whether these types of "claims" by the defendants were actually enhancements of a "substantially similar" product or nothing more than unsupportable, veiled marketing efforts.

Finally, in making the business decision to either enter the pelvic mesh market or spend the necessary resources to develop products which had been previously launched, at some point every defendant determined there was an unmet need in the market through consultation with its paid consultant-physicians, as well as physicians using any type of pelvic mesh products, to collaborate on areas of improvements to then-existing products. Particularly where these consultant-physicians worked for more than one defendant, any documents reflecting concerns expressed to one defendant related to another defendant's product(s) should be fair game in a

[5] Given that Bard recently moved to exclude every single expert retained by the bellwether plaintiffs and Ethicon filed 22 separate motions in limine in the first pelvic mesh state court trial in New Jersey, plaintiffs are confident the defendants will exhaust every possible efforts to limit the use of these documents at trial, to the extent they are inadmissible under the Federal Rules of Evidence.

deposition as to whether the expert informed the defendant about the warnings or risks he perceived at that time associated with the surgical implantation of the device. In sum, plaintiffs have certainly met the low relevance threshold under the Federal Rules.

B. Disclosure of "confidential" information to a competitor is a red herring.

Defendants go to great lengths to suggest that the limited use of certain "confidential" documents,[6] for example, would impact "trade secrets, marketing information, and high-cost competitive intelligence."[7] One might assume that the equivalent of the recipe for Coca-Cola was disclosed on an internal power point presentation, and that the other four defendants would immediately gain an advantage in the marketplace upon receipt of this defendant's successful 'formula.' However, at least with respect to the plaintiffs allegedly injured by defendants' devices in these MDLs, these products were complete failures. Moreover, the reality is that any relevant documents which would conceivably be utilized by plaintiffs in depositions are several years old and relate to pelvic mesh products which, by and large, are not even being sold. For example, as of 2012, Boston Scientific was only selling Uphold Lite; Ethicon 'voluntarily' withdrew its entire line of pelvic organ prolapse mesh products from the market last year as well; C.R. Bard withdrew the Avaulta products in 2012.

No defendant would be losing patent rights or giving away company trade secrets—that type of information has been unquestionably designated as "highly confidential." The criticisms of another product by either a fact witness or potential expert witness could not be remotely construed as "high-cost competitive intelligence." Thus, Defendants' concern that any defendant

[6] While making reference to the fact that Plaintiffs have not contested any specific documents which were improperly designated as "confidential," the unfortunate fact (previously acknowledged by the Court) remains that defendants have, generally speaking, engaged in a practice of over-designating confidential documents. It is disingenuous for defendants to make such argument when it iswell known that they have inappropriately designated millions of pages of documents as "confidential" and to expect the court to be willing orhave the time to peruse that magnitude of documents is not grounded in reality.

[7] Dkt No. 412 at p. 6.

would be in a position either to benefit from or feel threatened by the shared disclosure of the limited scope of documents requested by plaintiffs is over-exaggerated and unsupportable.

C. Defendants' lack of access to the other MDL databases is outweighed by the potential need to impeach defendants' experts or retained consultant-physicians on prior inconsistent statements.

There are numerous instances of defendants' retained consultant-physicians taking inconsistent positions on the purported benefits associated with a variety of the products at issue in these MDLs. For instance, where a consultant-physician for AMS notes to AMS employees that a Boston Scientific product has a number of flaws, then that same physician (when retained by Boston) tells Boston that the device is the best he has ever used, plaintiffs should be afforded the opportunity to highlight these inconsistencies in the witness' deposition. This would additionally allow the witness to explain the perceived inconsistency in the documents prior to its introduction at trial. To adopt defendants' position and disallow the use of either depositions or, more importantly, documents between the various MDLs would permit experts and consultant-physicians alike to selectively support a defendant's product only when convenient.

"Extrinsic evidence of a witness's prior inconsistent statement is admissible only if the witness is given an opportunity to explain or deny the statement and an adverse party is given an opportunity to examine the witness about it, or ***if justice so requires***." FED. R. EVID. 613(b) (emphasis added). To introduce a witness's own earlier statement for impeachment: (1) the statement must be inconsistent, (2) the inconsistency must be relevant, (3) the inconsistent statement must, on request, be disclosed to opposing counsel, the witness allowed to explain the inconsistency, and opposing counsel allowed to question the witness, and (4) the district court should instruct the jury about the limited purpose of the earlier statement. *U.S. v. Larry Reed & Sons Partnership*, 280 F.3d 1212, 1215 (8th Cir. 2002); *accord U.S. v. Rogers*, 549 F.2d 490,

495–98 (8th Cir. 1976). Allowing an expert witness or consultant-physician for the defendants to make one statement (or testify in a certain manner) about the development of a product and then make a substantially inconsistent statement about the same or similar product when testifying for another defendant would be manifestly unjust, make a mockery of the MDL courts, and contradict the intent behind the protective orders themselves if these inconsistent statements went unchallenged. As previously acknowledged by Magistrate Judge Stanley in a similar dispute involving AMS, even if not clearly inconsistent (*e.g.*, the red light-green light analogy), these types of statements could potentially implicate the credibility of the witness. *See* Memorandum Opinion and Pretrial Order # 12 (MDL 2325) at pp. 12, 15–16.

Defendants' argument regarding lack of notice of utilization of documents and lack of access to other databases is clearly outweighed by the need demonstrated by plaintiffs. However, in order to address the concerns outlined by defendants, plaintiffs propose that defendants affected by use of documents in a deposition shall not be bound by that deposition and allowed to take another deposition at a later date.

D. Defendants misinterpret their obligations as device manufacturers.

While not disputing defendants are required to keep abreast of "state-of-the-art" products and new discoveries in their field, defendants misinterpret plaintiffs' state-of-the-art argument. Documents produced across MDLs will help shed light on what the pelvic mesh manufacturers knew or should have known about these implantable devices at any given time. Where a defendant's retained physician was communicating known flaws or concerns to other manufacturers, the issue is whether these known concerns that were specifically communicated about a competitor's devices were still then incorporated into the defendant's product. The classic example in these cases is knowledge of mesh shrinkage related to pore sizes and the

weight of the mesh—given that this type of information was communicated to other defendants by their consultants, the issue becomes the time frame in which the defendant's failure to address these known concerns before launching a product into the market occurred. Plaintiffs will take the position that defendants knew or should have known that the smaller pore sizes and heavier weight mesh were never appropriate to be implanted in the human body, and certainly without any long-term clinical testing. The use of these documents will assist plaintiffs in demonstrating what a defendant knew or should have known at any given point.

CONCLUSION

For the foregoing reasons, plaintiffs respectfully request that the SPOs be amended to state that "confidential" documents may be used where relevant among the MDLs pending before this court.

This 29th day of April, 2013.

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CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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